16/Appeal Brief (3)

Docket No. 200427US0 CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Claudio CAVAZZA : EXAMINER: G. KISHORE

SERIAL NO: 09/777,874 :

FILED: FEBRUARY 7, 2001 : GROUP ART UNIT: 1615

FOR: PHARMACEUTICAL COMPOSITION COMPRISING CARNITINE OR ALKANOYL L-CARNITINE FOR THE PREVENTION AND TREATMENT OF DISEASES BROUGHT ABOUT BY LIPID METABOLISM DISORDERS

Bet 3-22-04

APPEAL BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

This is an appeal from the Rejection of the claims mailed May 8, 2001.

I. REAL PARTY IN INTEREST

The real party in interest is Sigma-Tau HealthScience S.P.A., Rome, Italy by assignment recorded reel/frame: 9490/0107 on October 6, 1998.

II. RELATED APPEALS

Appellants, Appellants' legal representative and their assignee are not aware of any appeals or interferences which will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF THE CLAIMS

Claims 11-18 and 20-31 are on appeal.

IV. STATUS OF THE AMENDMENT FILED UNDER 37 C.F.R. §1.116

The Amendment and Request for Reconsideration, filed June 6, 2002, was not entered.

V. THE APPEALED CLAIMS

A copy of the appealed claims is attached as Appendix I.

VI. PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Proposed finds of facts and conclusions of law are set forth in Appendix II. See Gechter v. Davidson, 43 USPQ2d 1030 (Fed. Cir. 1997) (attached).

VII. SUMMARY OF THE INVENTION

The invention is directed to compositions comprising the combination of hydroxycitric acid and acetyl-L-carnitine (see the specification, page 1, lines 10-20 of the specification). Acetyl-L-carnitine is described on page 2, lines 23 and 24 and its use in combination with hydroxycitric acid (calcium hydroxycitrate) is exemplified in Tables 1-5 on pages 16-20 of the specification.

The invention is also directed to methods of facilitating the metabolism of lipids, see page 5, lines 6-12, of the specification; methods for reducing food consumption and body weight increase, see page 6, lines 5-9 and Tables 1 and 2 on pages 16 and 17 of the specification; methods for reducing cholesterol and lipid (triglyceride) levels, see page 5, line

6-page 6, line 14 of the specification and Tables 3-5 on pages 18-20 of the specification. The synergistic effects provided by the invention are described on page 5, lines 13-16.

As shown by the experimental data in the present disclosure, e.g. Tables, 2, 4 and 5, the combination of hydroxycitric acid and acetyl-L-carnitine produces a statistically significant synergistic effect that administration of hydroxycitric acid alone, or acetyl-L-carnitine alone, does not.

The statistical significance of these experimental data is substantiated by the T-test results provided by the timely filed Declaration of January 2, 2002. This Declaration provides T-test values for the results reported in Tables 2, 4 and 5 on pages 17, 19 and 20 of the specification. The T test is a conventional test of the statistical significance of differences between groups, such as differences between a control group receiving hydroxycitric acid alone, or acetyl-L-carnitine alone, and an experimental group receiving the combination of hydroxycitric acid and acetyl-L-carnitine.

As shown by the present disclosure, the combination of acetyl-L-carnitine and hydroxycitric acid provides superior and synergistic effects on lipid metabolism, for instance, by decreasing weight gain and by providing superior reductions in triglyceride and cholesterol levels. Excess weight and high levels of triglycerides and cholesterol are associated with many diseases and disorders, thus reductions in these parameters reduce the risk of disease and enhance health.

VIII. THE ISSUE OF THIS APPEAL

The issues for adjudication by this appeal focus on whether or not the claimed compositions and methods are obvious. There are six separate obviousness rejections. However, the issues as pertaining to the composition claims and method claims have been

listed separately. For instance, Issues A1 and A2 correspond to the first obviousness rejection. Similarly, Issues B1 and B2 each correspond to the same rejection, as do Issues C1 and C2. Issue C1 and Issues D and E may be grouped and considered together, as each of these issues pertains to the same primary prior art references.

A1. Whether composition Claims 11-18, 20-24 and 31 are obvious over Wiegand, U.S. Patent 3,810,994 by itself, or in combination with Moffett, U.S. Patent 5,536,516.

A2. Whether method Claims 25-30 are obvious over Wiegand, U.S. Patent 3,810,994 by itself, or in combination with Moffett, U.S. Patent 5,536,516.

B1. Whether composition Claims 11-18, 20-24 and 31 are obvious over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 and/or Burtle, U.S. 5,030,657.

B2. Whether method Claims 25-30 are obvious over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 and/or Burtle, U.S. 5,030,657.

C1. Whether composition Claims 11-18, 20-24 and 31 are obvious over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 and/or Burtle, U.S. 5,030,657.

C2. Whether method Claims 25-30 are obvious over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 and/or Burtle, U.S. 5,030,657.

D. Whether composition Claim 18 is obvious over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or both, and further in view of page 4 of the specification.

E. Whether composition Claim 23 is obvious over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or

both, and further in view of Weiner (1989) by itself, or in combination with Stracher, U.S. Patent 5,008,288.

F. Whether method Claims 28-30 are obvious over Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657; or Wiegand, U.S. Patent 3,810,994, in view of Moffett, U.S. Patent 5,536,516; or Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand and/or Burtle, and further in view of Cavazza, U.S. Patent 4,268,524.

IX. GROUPING OF THE CLAIMS

The following groups of claims define separate and distinct inventions that do not stand or fall together with the other claims.

Claims 11-18, 20-24 and 31 are directed to compositions comprising hydroxycitric acid and acetyl-L-carnitine and do not stand or fall together with Claims 25-30, which are method claims, which recite distinct method steps.

Claim 25 is directed to method for facilitating the metabolism of lipids and does not stand or fall together with the composition claims, or the other method claims, which encompass distinct method steps.

Claim 26 is directed to reducing food consumption and does not stand or fall together with the composition claims, or the other method claims, which encompass distinct method steps.

Claim 27 is directed to method reducing body weight and does not stand or fall together with the composition claims, or the other method claims, which encompass distinct method steps.

Claim 28 is directed to method for reducing serum triglycerides and does not stand or fall together with the composition claims, or the other method claims, which encompass distinct method steps.

Claim 29 is directed to method for treating hypertriglyceridaemia and does not stand or fall together with the composition claims, or the other method claims, which encompass distinct method steps.

Claim 30 is directed to method for treating hypercholesterolaemia and does not stand or fall together with the composition claims, or the other method claims, which encompass distinct method steps.

X. ARGUMENTS IN TRAVERSAL OF THE REJECTIONS

Rejection--35 U.S.C. 103

Claims 11-18 and 20-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand, U.S. Patent 3,810,994 by itself, or in combination with Moffett, U.S. Patent 5,536,516. This argument addresses both Issues A1 and A2.

Wiegand does not disclose or suggest combination of hydroxycitric acid and acetyl-L-carnitine. Col. 2, lines 34-44, indicates that carnitine, as well as various esters of carnitine, including acetylcarnitine, might be used for treating obesity. Col. 3, lines 26-42, indicates that carnitine may be used in combination with a restricted caloric program or with various drugs or vitamins. However, Wiegand does not suggest combining acetyl-L-carnitine with hydroxycitric acid, or that such a combination would exhibit a synergistic effect on reducing body weight gain as shown in Table 2 on page 17 of the disclosure. Moreover, Wiegand does not suggest administering the combination of acetyl-L-carnitine and hydroxycitric acid for reducing triglyceride levels or for treating hypertriglyceridaemia or hypercholesterolaemia.

Similarly, Moffett does not disclose or suggest the combination of acetyl-L-carnitine and hydroxycitric acid. Moffett is generally directed to hydroxycitric acid concentrates. Col.

1, lines 11-15, indicates that hydroxycitric acid is an inhibitor of the synthesis of fat and cholesterol in rats. Col. 6, lines 60-65 indicate that hydroxycitric acid may be incorporated into snack bars and beverages.

Based on the Wiegand and Moffett one with ordinary skill in the art would not have been motivated to make the specific combination of acetyl-L-carnitine and hydroxycitric acid, because neither Wiegand or Moffett discloses or suggests (1) selecting acetyl-L-carnitine, as opposed to carnitine or another compound related to carnitine, (2) combining acetyl-L-carnitine with hydroxycitric acid, or (3) that the combination of acetyl-L-carnitine and hydroxycitric acid would exert the synergistic effects shown in the Declaration filed January 2, 2002, including providing synergistic decreases in body weight gain as shown in Table 2. For instance, the prior art does not suggest that the effects of acetyl-L-carnitine and hydroxycitric acid on lipid metabolism would be additive and not antagonistic. Moreover, with respect to the method claims, neither document suggests administering the combination of acetyl-L-carnitine and hydroxycitric acid for reducing triglyceride levels or for treating hypertriglyceridaemia or hypercholesterolaemia. Accordingly, the compositions and methods of the present invention are not obvious over the cited prior art.

However, even if there were some suggestion in the cited prior art to combine acetyl-L-carnitine with hydroxycitric acid, the cited prior art does not disclose or suggest the synergistic effects provided by the present invention.

For the convenience of the Board, the synergistic effects provided by the invention in decreasing body weight increase, lowering triglyceride levels and lowering cholesterol levels are summarized from Tables 2, 4 and 5 of the Declaration of January 2, 2002 and presented in the Table below. The **embolded** results in each Table below show the effects of the combination of acetyl-L-carnitine and HCA are far greater than the effects of either

compound alone. The reduction provided by each treatment compared to the control (no treatment) is shown in the right column. As seen in the two right hand columns, the reductions provided by the combination of acetyl-L-carnitine and HCA are significantly greater the combined reductions provided by acetyl-L-carnitine alone or HCA alone.

Table 2: Body Weight Increase	Level	Reduction	%
Control (no acetyl-L-carnitine or HCA)	62.8	-----	
Acetyl-L-carnitine only:	60.4	-2.4	3.8
HCA only:	46.6	-16.2	25.8
Combination of acetyl-L-carnitine and HCA:	31.6	**-31.2**	49.9
Table 4: Triglyceride level			
Control (no acetyl-L-carnitine or HCA)	195.8	-----	
Acetyl-L-carnitine only:	191.2	-2.4	1.2
HCA only:	170.6	-25.2	12.9
Combination of acetyl-L-carnitine and HCA:	120.4	**-75.4**	38.5
Table 5: Cholesterol level			
Control (no acetyl-L-carnitine or HCA)	270.5	-----	
Acetyl-L-carnitine only:	266.7	-3.8	1.4
HCA only:	196.6	-73.9	27.3
Combination of acetyl-L-carnitine and HCA:	150.5	**-120.0**	44.4

The Applicants have established the statistical significance of these results using the Students T-test as shown in the Declaration filed January 2, 2002. The T-test is a conventional statistical method for determining the significance of differences between groups, such as a control group that receives only hydroxycitric acid or only acetyl-L-carnitine, and an experimental group receiving a combination of hydroxycitric acid and acetyl-L-carnitine.

These T-test results form part of the factual evidence provided in the prior Declaration and must be considered by the Examiner, see MPEP 716.01. The Applicants submit that these T-test results are uncontroverted and definitively establish the statistical

validity of the synergistic results shown in Tables 2, 4 and 5 on pages 17, 19 and 20 of the specification.

The Examiner has concluded that the experimental data of Tables 2, 4 and 5 shows less than an additive effect for the combination of acetyl-L-carnitine and HCA "taking into consideration the stand deviation". However, he has not provided an adequate scientific or mathematical basis for this conclusion, particularly in view of the T-test scores showing statistical significance also shown in the Declaration. Thus, while the Examiner disagrees that the experimental date in Tables 2, 4 and 5 show any synergistic effect or even an additive effect, he has not made of record evidentiary support for his opinion and his exact methodology for rebutting the statistical significance of the Appellants' experimental data, see MPEP 2144.02 and 2144.03. Accordingly, as the cited prior art does not disclose or suggest the specific combination of acetyl-L-carnitine and hydroxycitric acid, disclose the superior synergistic effects of this composition for reducing weight gain, cholesterol levels and triglyceride levels, the Appellants respectfully request that this rejection be reversed.

Rejection--35 U.S.C. 103

Claims 11-18 and 20-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 and/or Burtle, U.S. 5,030,657. This argument addresses Issues B1 and B2.

Hastings does not suggest acetyl-L-carnitine or the combination of acetyl-L-carnitine and hydroxycitric acid, or the synergistic effects of this particular combination. While claim 1 refers to a weight loss composition comprising hydroxycitric acid and L-carnitine (not acetyl-L-carnitine), this patent does not disclose or suggest the combination of acetyl-L-carnitine and hydroxycitric acid. Moreover, there is no suggestion that the combination of

acetyl-L-carnitine and hydroxycitric acid would exert synergistic effects on body weight gain or synergistic effects on lowering cholesterol or triglyceride levels as shown in Tables 2, 4 and 5 of the specification.

Wiegand has been addressed above, and does not disclose or suggest hydroxycitric acid, the combination of acetyl-L-carnitine with hydroxycitric acid, or the synergistic effects provided by such a combination.

Burtle does not disclose or suggest hydroxycitric acid, the combination of acetyl-L-carnitine with hydroxycitric acid, or the synergistic effects provided by such a combination. Burtle is directed to a fish feed comprising L-carnitine (not acetyl-L-carnitine) and col. 6, lines 25-39, describes various forms of L-carnitine, including acetylated L-carnitine (line 26). However, there is no suggestion to specifically select acetyl-L-carnitine, as opposed to other forms of carnitines, no disclosure or suggestion to combine acetyl-L-carnitine with hydroxycitric acid, and no disclosure or suggestion of the synergistic effects of the present invention as shown in the Declaration of January 2, 2002.

One with ordinary skill in the art would not have been motivated to select the combination of acetyl-L-carnitine and hydroxycitric acid of the invention, based on the cited prior art, because this art alone or in combination, does not disclose the combination of hydroxycitric acid and acetyl-L-carnitine, does not suggest administering the combination of acetyl-L-carnitine and hydroxycitric acid for reducing triglyceride levels or for treating hypertriglyceridaemia or hypercholesterolaemia, nor suggest the synergistic effects provided by this combination. Accordingly, the Appellants respectfully request that this rejection be reversed.

Rejection--35 U.S.C. 103

Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or both, and further in view of page 4 of the specification.

Hastings, Burtle and Wiegand have been discussed above. Page 4 of the specification was cited for its teaching that HCA may be obtained from certain plant sources.

However, as set forth above, the cited prior, alone or in combination, does not suggest selecting the combination of hydroxycitric acid and acetyl-L-carnitine, nor the synergistic effects of this combination, the Appellants respectfully request that this rejection be reversed.

Rejection--35 U.S.C. 103

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or both, and further in view of Weiner (1989) by itself, or in combination with Stracher, U.S. Patent 5,008,288.

Hastings, Burtle and Wiegand have been discussed above.

Weiner is cited for teaching liposomes as drug delivery agents and Stracher as disclosing carnitine incorporation into liposomes. These secondary references do not disclose or suggest the combination of acetyl-L-carnitine and hydroxycitric acid.

As the cited prior, alone or in combination, does not suggest selecting the combination of hydroxycitric acid and acetyl-L-carnitine, nor the synergistic effects of this combination, the Appellants respectfully request that this rejection be reversed.

Rejection--35 U.S.C. 103

Claims 28-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657; or Wiegand, U.S. Patent 3,810,994, in view of Moffett, U.S. Patent 5,536,516; or Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand and/or Burtle, and further in view of Cavazza, U.S. Patent 4,268,524. Claim 28 is directed to a method for reducing serum triglycerides, Claim 29 to a method for treating hypertriglyceridaemia and Claim 30 to a method of treating hypercholesterolaemia.

Wiegand, Burtle, Moffett and Hastings have been addressed above. Briefly, these documents do not disclose or suggest compositions comprising acetyl-L-carnitine and HCA or suggest the synergistic properties of this combination on lowering triglyceride and cholesterol levels.

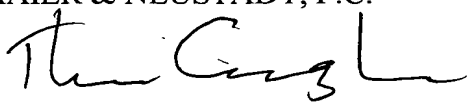
Cavazza is generally directed to a method of using acylcarnitines to increase levels of high-density lipoproteins. While Table 4 of Cavazza indicates the effects of acylcarnitines on serum lipids, it does not disclose or suggest the synergistic properties of the combination of acetyl-L-carnitine and HCA. As shown in Tables 4 and 5 of the Declaration, filed January 2, 2002, this combination provides highly significant reductions in triglycerides and cholesterol levels compared to acetyl-L-carnitine alone or HCA alone. The superior and synergistic effects of the combination of acetyl-L-carnitine and HCA are not suggested by Cavazza or the other cited prior art. Accordingly, the Appellants respectfully request that this ground of rejection also be withdrawn.

XII. RELIEF REQUESTED

Reversal of the Examiner's rejections of the appealed claims under 35 U.S.C. §103(a) is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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Attachment: Gechter v. Davidson, 43 USPQ 1030 (Fed. Cir. 1997)

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Appendix I: Appealed Claims 11-18 and 20-31

--11. (Amended) A composition comprising:

(i) a first component selected from the group consisting of acetyl L-carnitine, a salt thereof and an ester thereof; and

(ii) a second component selected from the group consisting of a hydroxycitric acid and a hydroxycitric acid derivative.

12. (Amended) The composition of Claim 11 that comprises acetyl-L-carnitine.

13. (Amended) The composition of Claim 11 that comprises a derivative of acetyl-L-carnitine.

14. (Amended) The composition of Claim 11 that comprises hydroxycitric acid or a salt or ester thereof.

15. (Amended) The composition of Claim 11 that comprises a pharmaceutically acceptable salt of acetyl L-carnitine selected from the group consisting of acetyl L-carnitine chloride, acetyl L-carnitine bromide, acetyl L-carnitine orotate, acetyl L-carnitine acid aspartate, acetyl L-carnitine acid phosphate, acetyl L-carnitine fumarate, acetyl L-carnitine lactate, acetyl L-carnitine maleate, acetyl L-carnitine acid maleate, acetyl L-carnitine acid oxalate, acetyl L-carnitine acid sulfate, acetyl L-carnitine glucose phosphate, acetyl L-carnitine tartrate, and acetyl L-carnitine acid tartrate.

16. (Amended) The composition of Claim 11 that comprises a second component selected from the group consisting of hydroxycitric acid, a salt of hydroxycitric acid, an ester of hydroxycitric acid, and a natural product or extract containing hydroxycitric acid or a salt or ester thereof.

17. (Amended) The composition of Claim 11 that comprises a second component that is calcium hydroxycitrate.

18. (Amended) The composition of Claim 16 that comprises a natural product or extract obtained from a fruit selected from the group consisting of Garcinia, Malabar Tamarind and gorikapuli.--

--20. (Amended) The composition of Claim 11, wherein the weight ratio of the second component to the first component is:

1:1 to 1:100.

21. The composition of Claim 11, further comprising a vitamin, mineral salt, antioxidant or vegetal fiber.

22. The composition of Claim 11, wherein said composition further comprises chromium.

23. The composition of Claim 11 in a solid, semisolid, liquid, semiliquid, powder, granular or lipsomic form.

24. (Amended) The composition of Claim 11 in the form of a tablet, capsule, granulate, or a powder.

25. A method for facilitating the metabolism of lipids, comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

26. A method for reducing food consumption comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

27. A method for reducing body weight comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

28. A method for reducing serum triglycerides comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

29. A method for treating hypertriglyceridaemia comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

30. A method for treating hypercholesterolaemia, comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

31. A vial comprising the composition of Claim 11.

Appendix II

A. Finding of Facts

1. That the T test results presented in the Declaration under 37 C.F.R. 1.132, filed January 2, 2002, establish significant differences between control groups receiving hydroxycitrric acid alone, or acetyl-L-carnitine alone, and groups receiving the combination of hydroxycitric acid and acetyl-L-carnitine.

2. That Table 2 of the Declaration under 37 C.F.R. 1.132, filed January 2, 2002, establishes that the administration of the combination of calcium hydroxycitrate and acetyl-L-carnitine produces significant decreases in weight gain compared to administration of hydroxycitric acid alone or acetyl-L-carnitine alone.

3. That Table 4 of the Declaration under 37 C.F.R. 1.132, filed January 2, 2002, establishes that the administration of the combination of calcium hydroxycitrate and acetyl-L-carnitine produces significant reductions in triglycerides compared to administration of calcium hydroxycitrate alone or acetyl-L-carnitine alone.

4. That Table 5 of the Declaration under 37 C.F.R. 1.132, filed January 2, 2002, establishes that the administration of the combination of calcium hydroxycitrate and acetyl-L-carnitine produces significant reductions in cholesterol compared to administration of calcium hydroxycitrate alone or acetyl-L-carnitine alone.

5. That none of the cited prior art discloses or suggests the synergistic effects provided by the combination of hydroxycitric acid and acetyl-L-carnitine as shown in Tables 1-5 of the disclosure and in the Declaration filed January 2, 2002.

6. That Wiegand, U.S. Patent 3,810,994, does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

6. That Moffett, U.S. Patent 5,536,516, does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

7. That Hastings, U.S. Patent 5,626,849, does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

8. That Burtle, U.S. Patent 5,030,657, does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

9. That Stracher, U.S. Patent 5,008,288, does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

10. That Weiner, Drug Development and Industrial Pharmacy (1989), does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

11. That Cavazza, U.S. Patent 4,268,524, does not suggest the combination of hydroxycitric acid and acetyl-L-carnitine, or the synergistic effects of such a combination.

B. Conclusions of Law

1. Several basic factual inquiries must be made in order to determine obviousness or non-obviousness of claims of a patent application under 35 U.S.C. §103. These factual inquiries are set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966);

> Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness of the subject matter is determined.

The specific factual inquiries set forth in Graham have not been considered and/or properly applied by the Examiner in formulating the rejection of the subject claims. Particularly, the scope and content of the prior art and the level of ordinary skill in the pertinent art were not properly determined, demonstrated and applied to the claimed invention. In the present case, proper consideration of the factual inquiries demonstrates the non-obviousness of the claimed invention.

2. That the compositions of Claims 11-18, 20-24 and 31 are not obvious over the cited prior art.

3. That the method of Claim 25 is not obvious over the cited prior art.

4. That the method of Claim 26 is not obvious over the cited prior art.

5. That the method of Claim 27 is not obvious over the cited prior art.

6. That the method of Claim 28 is not obvious over the cited prior art.

7. That the method of Claim 29 is not obvious over the cited prior art.

8. That the method of Claim 30 is not obvious over the cited prior art.

9. That the compositions of Claims 11-18, 20-24 and 31 are patentable.

10. That the methods of Claims 25-30 are patentable.

Gechter v. Davidson

U.S. Court of Appeals Federal Circuit
43 USPQ2d 1030

Decided June 12, 1997
Nos. 96-1374, -1375

Headnotes

PATENTS

1. Practice and procedure in Patent and Trademark Office -- Board of Patent Appeals and Interferences -- In general (§ 110.1101)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)

Board of Patent Appeals and Interferences is required to set forth in its opinions

specific findings of fact and conclusions of law adequate to form basis for review by U.S. Court of Appeals for the Federal Circuit, since mandate of 35 USC 114 that Federal Circuit "shall review" decision from which appeal is taken implies inherent power in Federal Circuit to require that such decision be capable of review, since, in view of that mandate, there is no reason to apply version of fact finding standard to board's decisions that is less demanding than standard applied to decisions of federal district courts, since standard does not exceed that applied to many other administrative tribunals, and since board has ability to set forth fact findings and conclusions of law at level of specificity equal to that required by

Fed.R.Civ.P. 52(a).

PATENTS

2. Practice and procedure in Patent and Trademark Office -- Board of Patent Appeals and Interferences -- In general (§ 110.1101)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)

Opinion of Board of Patent Appeals and Interferences concluding that claims corresponding to interference count were unpatentable over prior art reference under 35 USC 102 does not set forth specific findings of fact and conclusions of law adequate to form basis for review by U.S. Court of Appeals for the Federal Circuit, since board's opinion lacks claim construction, makes conclusory findings relating to anticipation, and omits any analysis on several claim limitations; anticipation analysis by board must be conducted on limitation by limitation basis, with specific fact findings for each contested limitation and satisfactory explanations for such findings, and claim construction must also be explicit, at least as to any construction disputed by parties to interference, or by applicant or patentee in ex parte proceeding.

Particular patents -- Electrical -- Call distribution system

5,036,535, Gechter, Fried, and Pokress, switchless automatic call distribution system, decision in interference holding patent invalid is vacated.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent interference no. 103,051 between Jerry Gechter, Robert L. Pokress, Jeffrey A. Fried, and G. Wayne Andrews (junior party), and Wayne A. Davidson and Diana S. Winter

(senior party). From decision holding independent claims corresponding to count unpatentable under 35 USC 102, parties cross-appeal. Vacated and remanded.

Attorneys:

William E. Booth, Robert E. Hillman, and Mary D. Mosley-Goren, of Fish & Richardson, Boston, Mass.; Barry E. Bretschneider, Washington, D.C., for appellants Jerry Gechter, Robert L. Pokress, Jeffrey A. Fried, and G. Wayne Andrews.

Charles L. Warren and Dennis J. Williamson, of Lucent Technologies Inc., Naperville, Ill., for cross-appellants Wayne A. Davidson and Diana S. Winter.

Judge:

Before Michel, Lourie, and Schall, circuit judges.

Opinion Text

Opinion By:

Michel, J.

On October 26, 1995, the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board) issued a decision in Interference No. 103,051, finding that the independent claims corresponding to the count were unpatentable under 35 U.S.C. Section 102 (1994) as anticipated by U.S. Patent No. 4,763,353 (Canale); the dependent claims fell by stipulation. Jerry Gechter, Robert L. Pokress, Jeffrey A. Fried, and G. Wayne Andrews (collectively, Gechter) appeal the unpatentability ruling which invalidates their U.S. Patent No. 5,036,535 (the '535 patent); Wayne A. Davidson and Diana S. Winter (collectively, Davidson) cross-appeal the same ruling which effectively rejects the claims in their application, Serial No. 07/748,147. The case was submitted for our decision after oral argument on March 7, 1997. Because the Board failed to set forth findings of fact adequate to enable us to determine whether its decision of anticipation is clearly erroneous, we vacate the Board's decision and remand the case for preparation of an opinion that makes the fact findings and claim construction necessary to make the decision reviewable on appeal.

BACKGROUND

The senior party, Davidson, provoked the interference by copying the claims of

Gechter's patent (the '535 patent) in his application. The claims of both Davidson and Gechter are directed to an automatic call distribution system that automatically distributes calls over a telephone network to a group of telephone operators who may be located distant from the central number and are waiting to receive calls. 1 The '535 patent has 63 claims, only claims 1 and 49 being independent. Claim 1, which corresponds exactly to the sole

count in the interference, recites:

An automatic call distributing system for automatically distributing telephone calls placed over a network to one of a plurality of agent stations connected to said network via network service interfaces and providing agent status messages to said network, said system comprising

receiving means connected via a network service interface to said network for receiving said agent status messages and call arrival messages from said network indicating that incoming calls have been made on said network, said agent status messages being generated at said agent stations and communicated through said network service interfaces and network to said receiving means, and

routing means responsive to said receiving means for generating a routing signal provided to the network to cause said network to establish a connection directly between said incoming call and an agent station through the network so that said connection is external of said routing means.

In its Final Decision, the Board found the independent claims corresponding to the count to be unpatentable to both Gechter and Davidson as anticipated by Canale. 2 The Board limited its anticipation analysis essentially to two paragraphs of its opinion. It focused on the findings that (1) Canale disclosed "agent status messages of these claims"; and (2) the claims corresponding to the count required only that the agent status messages have the same "content" throughout their transmission. The Board did not expressly construe the limitation, "agent status messages," before it determined that Canale reads on that limitation and the count. Gechter appeals from the Board's decision, arguing that the Board failed to interpret properly the limitation in light of his specification and therefore clearly erred in finding anticipation. Davidson cross-appeals, contending that if this court finds Gechter's claims corresponding to the count patentable over Canale, then it should also find that Davidson's claims corresponding to the count are patentable over Canale by reading the count in light of Davidson's specification. We have jurisdiction over this appeal pursuant to 35 U.S.C. Section 141 (1994) and 28 U.S.C. Section 1295 (a) (4) (A) (1994).

I.

Under 35 U.S.C. Section 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim. *In re Bond* , 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). As the Board's finding of anticipation presents a question of fact, this court's review is limited to deciding whether such finding was clearly erroneous. *In re King* , 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Implicit in our review of the Board's anticipation analysis is that the claim must first have been correctly construed to define the scope and meaning of each contested limitation. *See* , *e.g.* , *In re Paulsen* , 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (" [T]o properly compare [an allegedly anticipatory prior art reference] with the claims at issue, we must construe the term 'computer' to ascertain its scope and meaning."). Claim construction is a question of law and therefore reviewed *de novo* . *Markman v. Westview Instruments, Inc.* , 52 F.3d 967, 979, 34 USPQ2d 1321, 1329 (Fed. Cir. 1995) (in banc), *aff'd* , 116 S. Ct. 1384 [38 USPQ2d 1461] (1996).

A.

[1] The relevant statute and our own case law compel our vacatur of the Board's decision. By appealing the Board's decision to this court, Gechter invoked our jurisdiction under 35 U.S.C. Section 141, which provides that " [a] party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference may appeal the decision to the United

States Court of Appeals for the Federal Circuit." *See also* 37 C.F.R. Section 1.301 (1996). It then becomes our duty to review that decision for error. 35 U.S.C. Section 144 (1994) ("The United States Court of Appeals for the Federal Circuit *shall review* the decision from which an appeal is taken on the record before the Patent and Trademark Office." (emphasis added)). For an appellate court to fulfill its role of judicial review, it must have a clear understanding of the grounds for the decision being reviewed. *Cf. Atlantic Thermoplastics Co. v. Faytex Corp.* , 5 F.3d 1477, 1479, 28 USPQ2d 1343, 1345 (Fed. Cir. 1993) ("Here the court's opinion is too conclusory and sparse to provide a factual basis for determining whether the invention was on sale. . . ."). When the opinion explaining the decision lacks adequate fact findings, meaningful review is not possible, frustrating the very purpose of appellate review as well as this court's compliance with its statutory mandate. *Id.* Therefore, the statute's mandate to "review" implies inherent power in this court to require that the Board's decision be capable of review.

Necessary findings must be expressed with sufficient particularity to enable our court, without resort to speculation, to understand the reasoning of the Board, and to determine whether it applied the law correctly and whether the evidence supported the underlying and ultimate fact findings. If either the crucial findings on underlying factual issues or the ultimate finding of anticipation is clearly erroneous, the decision must be reversed. *See* , *e.g.* , *King* , 801 F.2d at 1327, 231 USPQ at 139 ("The board's finding of anticipation . . . cannot be clearly erroneous in the face of the supporting evidence."). Similarly, if the claims were misconstrued, a finding of anticipation must be reversed unless the error was harmless. *Rowe* , slip op. at 14 (Because of improper claim construction, "the Board clearly erred in its conclusion that the [prior art] patent anticipated Rowe's claims corresponding to the interference count [.]"); *see also In re Graves* , 69 F.3d 1147, 1152-53, 36 USPQ2d 1697, 1702 (Fed. Cir. 1995) ("In summary, we find that the Board's claim construction is reasonable, and its determination what [the prior art] teaches is not clearly erroneous. We cannot say, therefore, that the Board's conclusion that [the prior art] anticipates claims 4 and 6 is clearly erroneous.").

Although we have said we review decisions, not opinions, *King Instrument Corp. v. Otari Corp.* , 767 F.2d 853, 862, 226 USPQ 402, 408 (Fed. Cir. 1985), like a district court opinion, a Board opinion must contain sufficient findings and reasoning to permit meaningful appellate scrutiny. *See Bond* , 910 F.2d at 833, 15 USPQ2d at 1568 (because the Board made no finding that the delay means in the specification and that embodied in the prior art reference were structurally equivalent, "its decision as to the anticipation of claim 1 is deficient and must be vacated"); *cf. In re Alton* , 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996) (Board's decision vacated for failing to

articulate adequate reasons of why applicant's evidence failed to rebut the Board's prima facie case of inadequate description.).

B.

Analogous authority also supports our disposition. The standard of review of district court fact findings, set forth in Federal Rule of Civil Procedure 52(a), is the "clearly erroneous" standard. That is the same standard of review we apply to Board fact finding in both anticipation and obviousness contexts. Thus, Rule 52(a) and case law construing its requirements are instructive, even though not controlling, here. That rule requires that " [i]n all actions tried upon the facts without a jury or with an advisory jury, the court *shall find the facts specially* and *state separately its conclusions of law* thereon," Fed. R. Civ. P. 52(a) (emphasis added). Rule 52(a)'s purpose is, *inter alia* , to provide the appellate court with an adequate basis for review. *See Pretty Punch Shoppettes, Inc. v. Hauk* , 844 F.2d 782, 784, 6 USPQ2d 1563, 1565 (Fed. Cir. 1988) (" [T]he trial court must provide sufficient factual findings such that we may meaningfully review the merits of its order."). A district court therefore may not merely state its findings in conclusory terms, but must provide sufficient detail to elucidate the reasoning by which the court reached its ultimate finding on an issue of fact or conclusion on an issue of law; otherwise, the appellate court is unable to carry out its appellate review function. Indeed, as to the facts it must also find subsidiary facts "specially," and not just the ultimate fact, here of anticipation. If it fails to do so, its decision will ordinarily be vacated.

The same rule governs when a conclusion on a crucial issue of law is omitted. For example, in *Graco, Inc. v. Binks Manufacturing Co.* , 60 F.3d 785, 35 USPQ2d 1255 (Fed. Cir. 1995), we vacated the district court's judgment of patent infringement, because the district court's opinion was "absolutely devoid of any discussion of claim construction." *Id.* at 791, 35 USPQ2d at 1259.

In addition, the district court had focused its infringement analysis on only one claim limitation, and had concluded, without analysis, that that claim limitation was met by the accused device. *Id.* at 791, 35 USPQ2d at 1259-60. After noting that such a conclusory finding was entirely inadequate under Fed. R. Civ. P. 52(a), we concluded: "The entire omission of a claim construction analysis from the opinion, and the conclusory factual findings on infringement, each provide an independent basis for remand. Because insufficient findings preclude meaningful review by this court, we remand." *Id.* ; *see also Oakley, Inc. v. International Tropic-Cal, Inc.* , 923 F.2d 167, 168, 17 USPQ2d 1401, 1403 (Fed. Cir. 1991) (preliminary injunction vacated because district court's findings of fact and conclusions of law were insufficient to allow meaningful appellate review).

Similarly, in *Loctite Corp. v. Ultraseal Ltd.* , 781 F.2d 861, 228 USPQ 90 (Fed. Cir. 1985), we vacated the district court's invalidity decision under 35 U.S.C. Section 103 (1994) for failure to set forth findings on the four factual inquiries delineated in *Graham v. John Deere Co.* , 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). In assessing the adequacy of the lower court's findings to support its obviousness determination, we reasoned that "we must be convinced from the opinion that the district court actually applied *Graham* and must be

presented with enough express and necessarily implied findings to know the basis of the trial court's opinion." *Loctite* , 781 F.2d at 873, 228 USPQ at 98. In *Loctite* , because the district court "virtually abandoned" the *Graham* fact finding requirements, we vacated its obviousness holding for failure to comply with Rule 52(a) and remanded for the district court to make specific findings for each *Graham* inquiry. *Id.*

In light of this court's statutory mandate to "review" decisions from the Board, we see no reason in law or logic to apply a less demanding version of the fact finding standard to the Board's decisions any more than we would apply a lesser version of the clearly erroneous review standard. As we have said, "the decisions of the PTO boards have been reviewed on the record [by this court], by the same standards as applied to a decision from a district court[.]" *In re Leuders* , No. 96-1391, slip op. at 12-13 [42 USPQ2d 1481] (Fed. Cir. April 24, 1997) (discussing obviousness); *see* 35 U.S.C. Section 144; *see also* 9A Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* Section 2573, at 484-85 (1995) (" [Rule 52's] application to patent cases has never been doubted, and a principle substantially similar to Rule 52 governs the effect to be given the findings of the Patent Office in the district court." (footnotes omitted)). It is, of course, true that the Board is not bound by the Federal Rules of Civil Procedure, which by their terms apply only to the district courts. Nor, like the PTO Trademark Trial and Appeal Board, has the Board voluntarily bound itself to them. *See* 37 C.F.R. Section 2.116 (1996). But the Board must nevertheless meet an equivalent standard.

From a practical, judicial policy standpoint, moreover, patentability (validity) issues such as anticipation, whether decided by the Board or by district courts, should be reviewed similarly. If we did not require the Board to adhere to the same level of specificity in explicit fact findings and legal conclusions to support an anticipation finding, appellate review of the very same claim might produce disparate results, depending simply on which tribunal decided the issue. *See Leuders* , slip op. at 18-19 ("clear error" standard of review should apply to Board fact findings in order to maintain consistency with standard of review for district court fact findings). Our holding avoids this kind of disparity.

Nor does the standard we apply today exceed that applied to many other administrative tribunals. "It is well established that agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action." *Mullins v. United States Dep't of Energy* , 50 F.3d 990, 992 (Fed. Cir. 1995) (citing *SEC v. Chenery Corp.* , 318 U.S. 80, 94 (1943)). Furthermore, we assume the Board's ability to set forth fact findings and conclusions of law at the level of specificity equal to that required by Rule 52(a). Many Board members, now known as "Administrative Patent Judges," are experienced former senior examiners. Due to their technical expertise as well as their opinion writing experience as administrative judges, they are more than capable of providing the adequate fact finding required by our cases reviewing the PTO Board, and also called for regarding other tribunals in Rule 52(a) and administrative law decisions. *See* 35 USC Section 7(a) (1994) ("The examiners-in-chief shall be persons of competent legal knowledge. . . ."). Moreover, in the past we have required administrative judges of other boards to set forth adequate findings of fact to support their decisions. *See* , *e.g.* , *RMI, Inc. v. United States* , 800 F.2d 246, 250 (Fed. Cir. 1986) (decision vacated and remanded to the Armed Services Board of

Contract Appeals because of inadequate findings of fact).

II.

Judged under the standard set forth above, the Board's opinion lacks the level of specificity necessary for our review. In concluding that the claims corresponding to the count were unpatentable over Canale under 35 U.S.C. Section 102, the Board provided only the following, limited analysis:

With respect to Gechter's argument, it is considered that the [prior art] reference discloses the agent status messages of these claims. . . . Although the electrical signals representative of the [prior art] messages may be modified by controller 102, the message content of the agent status messages derived from the agent positions 103-1 to 103-n (the line status changes as they occur) remains the same when forwarded to the receiving means 108 (station set interface). Thus, the agent status messages received by means 108 are the same messages originating with the agent stations.

Notably absent from the Board's opinion is any explanation for whether, how, and why Canale contains each of the other limitations of the claim. Yet the Board does not say their presence in Canale was conceded. Moreover, the Board's only other attempted justification appears in a footnote to its opinion, asserting that "neither party has argued that the Canale reference does not include a written description of an equivalent structure" of the means-plus-function recitations in the independent claims. Nevertheless, to hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference. *Bond* , 910 F.2d at 832, 15 USPQ2d at 1567.

[2] In the present case, the Board's opinion lacks a claim construction, makes conclusory findings relating to anticipation, and omits any analysis on several limitations. For example, the Board opinion does not separately construe the term "agent status messages" before finding that Canale discloses just such "agent status messages." In addition, the Board never construed the scope of the structures disclosed in the specification for the claimed "receiving means," nor did the Board expressly find that the "receiving means" disclosed in the specification was structurally equivalent to that embodied in Canale. Moreover, the Board's opinion also failed to define the exact function of the receiving means, as well as to find that Canale disclosed the *identical* function. *See Pennwalt Corp. v. Durand-Wayland, Inc.* , 833 F.2d 931, 934, 4 USPQ2d 1737, 1739 (Fed. Cir. 1987) (in banc) (means-plus-function limitation covers structure that performs the identical function and is the same structure described in the specification or an equivalent thereof). The parties contest these issues on appeal, but the relevant findings were omitted from the Board's opinion. In *Bond* , this court vacated the Board's anticipation decision because it failed to make one particular subsidiary finding. In that case, the Board determined that a prior art reference anticipated the applicant's claimed telephone answering machine, finding that the reference disclosed the claimed "delay means." 910 F.2d at 833, 15 USPQ2d at 1568. The delay means disclosed in the reference, however, was not identical to the delay means in the specification. This court

vacated the Board's anticipation decision because the Board made no specific finding that, pursuant to 35 U.S.C. Section 112, Para. 6 (1994), the delay means in the specification and that embodied in the prior art reference were structurally equivalent. *Id.* Here, the Board's opinion omits not one, but several crucial findings. We therefore must vacate and remand.

CONCLUSION

In sum, we hold that the Board is required to set forth in its opinions specific findings of fact and conclusions of law adequate to form a basis for our review. In particular, we expect that the Board's anticipation analysis be conducted on a limitation by limitation basis, with specific fact findings for each contested limitation and satisfactory explanations for such findings. 3 Claim construction must also be explicit, at least as to any construction disputed by parties to the interference (or an applicant or patentee in an ex parte proceeding). *VACATED AND REMANDED* .

COSTS

Each party shall bear its own costs for this appeal.

Footnotes

Footnote 1. Because the disposition of this case rests on reviewability, not the merits, we do not describe the technology and discuss the facts only as necessary for this decision.

Footnote 2. The PTO may, during the course of an interference, determine the patentability of any claim involved in the interference. *See Rowe v. Dror* , No. 96-1304, slip op. at 5 [42 USPQ2d 1550] (Fed. Cir. April 21, 1997); *see also* 37 C.F.R. Sections 1.633(a), 1.641 (1996). Because the parties stipulated that the patentability of all of the dependent claims would rise or fall with that of the independent claims, the Final Decision of the Board was dispositive of the entire interference.

Footnote 3. While not directly presented here, obviousness determinations, when appropriate, similarly must rest on fact findings, adequately explained, for each of the relevant obviousness factors in the Supreme Court's decision in *Graham* , 383 U.S. at 17-18, 148 USPQ at 467, and its progeny in this court, *see* , *e.g.* , *Loctite* , 781 F.2d at 872, 228 USPQ at 97.

- End of Case -

